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GLUCOSENS study protocol: a continuous glucose monitoring system compared to fingerstick glucose monitoring in surgical wards – a two-centre before-after clinical trial

Helen Schultz ,[1,2] Marian Christin Petersen,[3,4] Kasper Baasch Nielsen,[5] Line Abrahamsen,[1] Torill Donslund Nielsen,[6] Ulla Linding Joergensen,[5] Tine Lumbye Thomsen,[3] Karoline Schousboe[2,5]

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For numbered affiliations see end of article.

Correspondence to
Dr Helen Schultz;
helen.schultz@rsyd.dk

ABSTRACT

Introduction Effective glucose control in surgical patients at risk of hyperglycaemia and hypoglycaemia is crucial, as these conditions can lead to surgical site infections, prolonged hospital stays and death. Fingerstick glucose monitoring (FSGM), the standard measurement of glucose, can be painful for patients and time-consuming for nursing staff, especially with hourly monitoring around surgery. Continuous glucose monitoring systems (CGMS) offer a less invasive alternative with better glucose regulation in outpatients.

The GLUCOSENS study compares the effects of CGMS and FSGM on point-of-care measurements and time-in-range (3.9–10.0 mmol/l) glucose levels (primary outcome), patient satisfaction and experience and nursing staff workload and experience in surgical wards. Furthermore, it evaluates CGMS accuracy during perioperative periods and medical imaging.

Methods and analysis This Danish two-centre study will be conducted at the general surgical wards of Odense and Zealand University Hospital and will involve 305 patients over 18 months. The study is divided into three periods: first, a standard care period with point-of-care FSGM (110 patients); second, an intervention period with point-of-care CGMS (110 patients); third, another standard care period with point-of-care FSGM combined with a blinded sensor for comparing continuous glucose data from this period with continuous glucose data from the intervention period (85 patients). Furthermore, the study will include 24 nursing staff.

Data will be collected through medical file reviews on glucose levels, patient satisfaction questionnaires, a patient field study, an observation study of the nursing staff's workload and qualitative interviews of nursing staff.

Ethics and dissemination The study is registered with the Records of Processing Activities in the Region of Southern Denmark for research and quality projects (ID number: 23/36734) and has been approved by the Regional Scientific Ethical Committee in Southern Denmark (ID number: S-20240041). The results will be published in international peer-reviewed journals.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The two-centre study design, with four in-bed units, strengthens the generalisability of the study results, as participants are included from several units with different cultures.
⇒ The study employs a mixed-methods approach, integrating both quantitative and qualitative methods.
⇒ The narrow inclusion criteria, with an expectation of at least three daily measurements for 3 days, may limit the generalisability of the study results.
⇒ The non-randomised controlled design and, thus, the potential impact of seasonal variation may bias the results.

Trail registration number ClinicalTrials.gov Registry (NCT06473480)

INTRODUCTION

Glucose control in surgical patients at risk of hyperglycaemia and hypoglycaemia is essential, as these conditions can lead to infections, poor surgical outcomes, prolonged hospital stays and death.[1 2] In 2022, the prevalence of diagnosed diabetes in Denmark was 6.2%.[3] With the global incidence of diabetes on the rise,[4–7] the number of patients requiring glucose control during surgical admissions is increasing.

Point-of-care (POC) fingerstick capillary glucose monitoring (FSGM) is standard in many hospitals[8 9]; however, FSGM can be painful, disrupt sleep and increase postoperative stress for patients.[10 11] Additionally, it can be time-consuming, requiring up to 2 hours of nursing work per patient daily.[12] This makes timely and prescribed glucose monitoring challenging in busy surgical wards, potentially leading to untreated hyperglycaemia

and hypoglycaemia. Moreover, FSGM provides only a snapshot of glucose levels, without indicating whether glucose is stable, rising or falling.

An alternative to FSGM is continuous glucose monitoring systems (CGMS), which measure glucose levels via a subcutaneous sensor every few minutes. CGMS is predominantly used in ambulatory settings and has been shown to improve glucose regulation.[13 14] Several studies have confirmed the accuracy of CGMS compared with FSGM in surgical and medical wards, reporting an overall mean absolute relative difference ranging from 9.4 to 12.9, making it acceptable for use in surgical wards.[13] Other studies have reported that CGMS in surgical and medical wards resulted in superior glycaemic control and reduced hypoglycaemia, insulin usage and in-hospital complications and detected significant duration of both hypoglycaemia and hyperglycaemia despite protocolised perioperative diabetes management compared with FSGM.[15–17]

Studies on patients' perspectives of CGMS have been limited to everyday life and outpatient settings. One review on patients with type 1 and 2 diabetes reported improved convenience, control and freedom by the use of CGMS but also reported being overwhelmed by data and frustrated by inaccuracy and technical issues,[18] which is consistent with findings from another review of patients with diabetes type 2.[19] Another study reported that patients with type 2 diabetes found the technology helpful for disease management, although it could also serve as an unpleasant reminder of disease progression and cause discomfort.[20]

One case report has described nurses' experiences with CGMS in hospital wards for patients with type 1 diabetes. The nurses experienced an increased workload due to difficulties hearing the device receiver, leading to more frequent patient observations.[21]

In summary, CGMS have been reported to be safe and beneficial in ambulatory settings, while challenges and knowledge gaps remain in hospital wards. To date, no studies have compared glucose levels from CGMS with those from a laboratory plasma glucose analyser as the reference. This study aims to investigate the effect of CGMS compared with FSGM in patients with hyperglycaemia in general surgical wards on glucose levels, complications, length of hospital stay and patient satisfaction and experience with glucose management during hospitalisation and up to 3 months after discharge. Additionally, the study will investigate the nursing staff's workload and experience in the surgical ward and the accuracy of CGMS throughout hospitalisation, including during surgical procedures and medical imaging.

METHODS AND ANALYSIS

Design

The study employs a two-centre before-after intervention design. A cluster randomised control trial design was not appropriate because the study investigates nursing staff workload and experience with two glucose monitoring methods, which could be affected if the nurses need to continuously switch between the two procedures in a busy surgical ward.

The study comprises seven substudies conducted over three distinct time periods across 18 months (figure 1). Three time periods are needed as different patient perspectives are investigated in period 1 with standard care, and the use of a blinded sensor in this period may influence these results. Consequently, an additional period of standard care with FSGM combined with a blinded sensor is added (period 3). We used the Standard Protocol Items: Recommendations for Interventional Trials checklist when writing this paper.[22]

Hypothesis

We hypothesise that CGMS are beneficial in surgical wards and will result in (a) better glycaemic control, which will lead to fewer complications and shorter hospital stays, (b) improved satisfaction and experience for patients and (c) decreased workload and better experience for surgical nursing staff. Additionally, we hypothesise that the accuracy of CGMS compared with FSGM is acceptable throughout the inpatient surgical trajectory.

Study setting

The study will be conducted in Danish general surgical wards at Odense University Hospital (OUH), which has three in-bed units, and in one in-bed unit at Zealand University Hospital (SUH Køge). There are approximately 85 beds in total. The departments receive acute and elective patients with upper and lower malign and non-malign gastrointestinal diseases. At OUH, the rooms for patients have one, two or four beds, whereas they all have one bed at SUH. Glucose measurements are performed according to prescriptions by the surgeon, but extra measurements can be performed at the discretion of the staff.

Study period 1: standard care

For patients with diabetes or hyperglycaemia, the recommendations for the number of glucose measurements are at least four times per day at OUH and three times per day at SUH. During fasting, the recommendation is hourly measurement in all study settings. At OUH, glucose monitoring and management prescriptions for the correctional insulin dosing are documented in a medical file with a referral to a schedule (figure 2) that can be adjusted to individual needs. This schedule is placed at the bedside, where the nursing staff performs the documentation. At SUH, glucose monitoring and management are provided according to individual prescriptions, with documentation made by nurses in an office or medication room. If more than one glucose measurement is above 10 mmol/L, specialised diabetes nurses will come to the surgical ward and conduct supervision on the following weekday, and thereafter as often as they consider it clinically relevant.

PERIOD 1: Point-of-care fingerstick glucose monitoring = standard care (OUH + SUH)*		
June – December 2024	**Substudy 1:** Glucose levels and management for surgical patients in relation to hospitalisation.	110 patients
	Substudy 2: Patient satisfaction with glucose monitoring and management in surgical wards.	
	Substudy 3: Nursing staff's workload related to glucose monitoring and management in surgical wards.	
	Substudy 4: Patient experience of glucose monitoring and management in relation to hospitalisation in surgical wards.	14 of the 110 patients

↓

PERIOD 2: Continuous glucose monitoring system as point-of-care = study intervention (OUH + SUH)*		
January – July 2025	**Substudy 1:** Glucose levels and management for surgical patients in relation to hospitalisation.	110 patients
	Substudy 2: Patient satisfaction with glucose monitoring and management in surgical wards.	
	Substudy 3: Nursing staff's workload related to glucose monitoring and management in surgical wards.	
	Substudy 4: Patient experience of glucose monitoring and management in relation to hospitalisation in surgical wards.	20 of the 110 patients
March 2025	**Substudy 7:** Nursing staff's experience of glucose monitoring and management in surgical wards.	24 nursing staff

↓

PERIOD 3: Point-of-care fingerstick glucose monitoring = standard care + blinded sensor (OUH)*		
August - December 2025	**Substudy 5:** Continuous glucose levels for surgical patients during hospitalisation in surgical wards	85 patients
	Substudy 6: Accuracy of a continuous glucose monitoring system for surgical patients during hospitalisation	

*OUH = Odense University Hospital / SUH = Zealand University Hospital

Figure 1 The design and flow of study periods and substudies.

In all units, the standard care for blood glucose monitoring is POC FSGM at the time points shown in figure 2. An Accu-Chek Inform II monitor or HemoCue Glucose 201 DM RT System, which automatically transfers the glucose level in real-time to the medical file, is used. Equipment for glucose monitoring is brought to the patient at each monitoring session, and a personal fast-acting insulin pen is kept permanently next to the patient.

At discharge from OUH, patients who reside within OUH's admission area and are treated with insulin are offered a 3-month follow-up visit at Steno Diabetes Center Odense or the department of endocrinology outpatient clinic, OUH Svendborg. This replaces the routine follow-up visit at their GP or outpatient departments. The follow-up includes the standard blood tests including HbA1c measurement. Additionally, the patients can contact the two settings by phone between discharge and their follow-up visit, if needed.

Glucose monitoring x8	BG*	Insulin	Signature	Comment
At 3 am				
Before breakfast				
At 9.30 am				
Before lunch				
At 1.30 pm				
Before supper				
At 7 pm				
Before bedtime				
Glucose monitoring x5: At 3 am, before meals, and before bedtime				
Glucose monitoring x4: Before meals and before bedtime				

NovoRapid (NR) after schedule	
BG* under 4	No insulin
BG* between 4 – 8	NR: 2 IE
BG* between 8 – 12	NR: 4 IE
BG* between 12 – 16	NR: 6 IE
BG* over 16	NR: 8 IE

* BG = Blood glucose

Figure 2 Blood glucose monitoring and management after a schedule. IE, International unit; NR, NovoRapid.

Figure 3 A continuous glucose monitoring system with a sensor and a scanner—FreeStyle Libre 2.

Study period 2: CGMS

Patients will receive a CE-marked FreeStyle Libre System 2 Plus, which includes a sensor and a scanner, as the CGMS (figure 3). The sensor is provided to the patient on inclusion in the study and is placed subcutaneously on the back of the patient's upper arm with a single stick by assigned study nurses. The maximum duration of use for one sensor is 15 days. Following a 1 hour training session and a written guideline, the surgical nursing staff will use a scanner to read the subcutaneous glucose concentration measured by the sensor.[23] The CGMS can monitor glucose levels every minute; however, the organisation and staffing of the surgical wards do not allow for continuous monitoring of the CGMS, either bedside or via an online monitor in the surgical nurses' office. Consequently, CGMS alarms will not be activated. Instead, the surgical nursing staff will scan the sensor for glucose concentration at the same time points as in standard care with the possibility of adjusting the number of measurements to individual needs. Specialised diabetes nurses will perform an upload of the continuous glucose levels from the scanner and will supervise the surgical staff and patients based on these readings.

Documentation of glucose monitoring and management will follow standard care procedures, except at SUH, where the nursing staff will document glucose levels in the medical record manually, as the CGMS is not integrated with the system.

During hospitalisation, scanning of the sensor will stop when the surgeon directs this, typically when the patient's glucose readings are persistently within the normal range. The sensor will remain on the patient for a maximum of 15 days in case of re-prescription of glucose monitoring. If glucose monitoring is required for more than 15 days, the sensor can be replaced once. Otherwise, sensors will be removed at discharge from SUH and from patients at OUH if they are not treated with insulin at discharge or living outside the OUH admission area.

Patients discharged from OUH who reside within OUH's admission area and who are treated with insulin are offered CGM for 3 months after discharge. These patients are supervised by diabetes nurses on how to use CGM at home and are offered the same 3 month follow-up visit as in standard care.

Study period 3: standard care combined with a blinded sensor

Only patients from OUH are included in this study period (figure 1). During hospital stay, the patients receive a blinded, CE-marked FreeStyle Libre Pro sensor, which does not display real-time glucose readings to either the patients or the professionals while in use. Therefore, standard care with POC FSGM is the basis for glucose management. The sensor is applied and removed from the patients in the same manner as in study period 2. Patients within OUH's admission area who are treated with insulin at discharge will have the blinded sensor replaced both at discharge and at home 14 days prior to the follow-up visit.

Recruitment of participants

We aim to recruit 305 patients from June 2024 to December 2025. The inclusion criterion is hospitalised patients aged 18 years or older, with or without previously diagnosed diabetes, for whom the surgeon has initially prescribed glucose measurements at least four times per day at OUH and three times per day at SUH (due to different hospital guidelines) and an expected glucose monitoring of at least four times per day at OUH and three times per day at SUH for a minimum of 3 days in the surgical department. Patients must be able to communicate in Danish and have signed a declaration of consent to study participation (see online supplemental material 'Participant consent form'). Exclusion criteria include cognitively impaired patients, those requiring glucose monitoring solely due to parenteral nutrition treatment, and patients admitted with a CGM. Furthermore, patients from the FSCM group cannot be included in the CGMS group.

In each unit, two to three assigned nurses will, when available, continuously invite eligible patients to participate. They will follow written guidelines, providing both oral and written information about the study. Written consent will be obtained once the patient agrees to participate. Patients will be approached within the first 24 hours after arrival in the surgical ward and will be offered up to 24 hours to consider participation in period 1 with standard care (figure 1) but only 4 hours in periods 2 and 3. The shorter time for consideration in periods 2 and 3 is due to the need to collect sufficient data on glucose levels for patients with an expected 3-day hospital stay. Additionally, the shorter consideration time in period 2 is necessary to end FSGM as soon as possible, ensuring that patient satisfaction (substudy 2) and patient experience (substudy 4) are not biased in the CGMS group.

The aim is to include 24 nursing staff in March 2025. The inclusion criterion for nursing staff is at least 1 month of experience with both glucose monitoring methods. A PhD student will invite eligible nursing staff to participate and conduct the interviews, providing both oral and written information about the study and obtaining written consent.

Data collection and outcome measures

The study includes seven substudies (figure 1), five of which use quantitative methods and two of which use qualitative methods.

Substudy 1: medical file review and glucose levels

The aim of this study is to compare POC glucose levels and management when performing POC FSGM and POC CGMS during hospitalisation and POC FSGM and CGM up to 3 months after discharge. The hypothesis is that POC CGMS and CGM will decrease the time with hyperglycaemia and hypoglycaemia during the surgical patient trajectory. Outcome measures are shown in figure 4.

Data are collected through a medical file review. At admission, data collection includes gender, age, body mass index (BMI), diagnosis, HbA1c level, diabetes type if diagnosed prior to admission, reason for glucose measurement and usage of both long-acting and short-acting insulin, as well as other diabetes treatments other than insulin. During hospitalisation, data collection consists of the date and time of surgery, CT, MR and positron emission tomography-CT scans, daily prescribed and actual glucose readings, glucose levels, glucose management at hypoglycaemia, doses of fast-acting and long-acting insulin, non-insulin diabetes treatment and registration of the blood samples: leucocytes, C reactive protein, creatinine and estimated glomerular filtration rate (eGFR). Additionally, if antibiotic treatment is prescribed, it is categorised as prophylactic or based on suspicion of infection. Temperature measurements are recorded for both morning and afternoon, along with daily weight. Any extra glucose measurements beyond those prescribed are documented, including the reason for these tests.

Data on complications include acute kidney injury (defined as a rise in plasma creatinine >26.5 µmol/L within 48 hours, a rise in plasma creatinine ≥50% within 7 days from the patient's baseline value or urine production <0.5 mL/kg/hour over 6 hours), sepsis, admission to the intensive care unit (duration and frequency), ketoacidosis, anastomosis leakage, bedsores and other issues. Furthermore, data on the length of hospital stay, readmission within a month and death while admitted and up to 90 days after discharge are included. The study includes 220 patients: 110 in the POC FSGM group and 110 in the POC CGMS group.

Substudy 2: questionnaire study of patient satisfaction

This study aims to compare patient satisfaction with POC FSGM versus POC CGMS during admission in surgical wards. We hypothesise that patients in the POC CGMS group will report higher satisfaction levels. To measure this, the validated Danish version of the 22-item Diabetes Treatment Satisfaction Questionnaire for Inpatients (DTSQ-IP)[22] is used. The patients complete the questionnaire around discharge, either on an iPad into a REDCap database or on paper, based on their preferences. If a patient is discharged without completing the questionnaire, an assigned nurse will follow-up by phone the next day to ensure its completion (see figure 4 for outcome measures). Furthermore, data collection includes patient education, employment status and living arrangements. The study includes the same 220 patients as in substudy 1.

Substudy 3: observation study and nursing staff's workload

This observational study aims to compare the nursing staff's workload when using POC FGSM versus POC CGMS for admitted surgical patients. The hypothesis is that CGMS will reduce time spent on glucose monitoring for surgical nursing staff while remaining the same for diabetes nurses. The outcome measures are shown in figure 4.

Data are collected from the same 220 patients as in substudy 1. The nurses assigned to the study observe three bedside glucose monitoring procedures performed by surgical nursing staff for each patient. Data collection includes the nursing staff's job title and activities performed during the procedure. During the glucose monitoring procedure, the time points and activities are recorded in the REDCap database using an iPad. Diabetes nurses document the time they spend in the surgical ward supervising patients and staff, as well as the time they spend consulting with endocrinologists about each surgical patient.

Substudy 4: qualitative field study of patient perspective

This qualitative field study includes participant observation and qualitative interviews and aims to explore the patient perspective on glucose monitoring, management and supervision with POC FSGM, POC CGMS and CGM during the surgical patient trajectory. Additional inclusion criteria for this study are patients treated with insulin at discharge and OUH patients residing within the OUH admission area.

During the stay in the surgical ward, participant observation of POC FSGM and POC CGMS is conducted up to a few days before expected discharge. This observation aims to explore actions, interactions and communication between patients and surgical nurses or certified nursing assistants in situations related to glucose monitoring, management and supervision of diabetes treatment for home self-care. Data are collected by field notes and include Spradley's dimensions for observation.[24]

Around discharge, a face-to-face qualitative semistructured interview is conducted. The research question is: how do patients experience glucose monitoring and management, information and supervision in diabetes treatment and interactions with surgical nursing staff and diabetes nurses in the surgical ward?

One month after discharge, a second qualitative semi-structured interview is conducted either face-to-face or online with the research question: how do patients experience glucose monitoring and management at home and how is information about diabetes treatment provided in

Primary outcome	Secondary outcome
Substudy 1 – medical file review	
Mean daytime and nocturnal POC glucose levels	**During hospitalisation:** • Mean dose of short- and long-acting insulin (IE) • eGFR • Complications: sepsis, acute kidney failure, acute transfer to intensive care unit, infection (CRP, leucocytes, central body temperature, received antibiotics), other (bedsore, diabetic ketoacidosis (pH < 7.30 and blood ketones > 3 mmol/L), anastomotic leak, and mortality • In-hospital mortality **After discharge** • TIR and other established outcomes derived from CGM • One-month re-admission • Three months mortality
Substudy 2 – questionnaire study	
Patient-reported outcome of glucose monitoring convenience	• Treatment satisfaction (item 1), • Experience with hyper- and hypoglycemic (items 2-3) • Treatment surveillance and flexibility (items 5+9) • Treatment information, knowledge, and communication (items 15-18) • Contact with specialized diabetes nurses (items 20-21) The scale is ranging from 0 – 6.
Substudy 3 – Observation study	
Mean minutes spent on bedside glucose monitoring	• The mean minutes surgical nursing staff spent on reporting glucose levels and management to diabetes nurses. • The mean minutes diabetes nurses spent collecting information about glucose levels and management, supervising patients and surgical professionals, and being supervised by endocrinologists.
Substudy 5 – Medical file review	
Percentage of time in range (3.9-10.0 mmol/l) during the entire hospital stay	• Percentage of time above range (TAR)10,1-13.9 mmol/L • Percentage of time above range (TAR) >13.9 mmol/L • Percentage of time below range 3.0-3.9 mmol/L • Percentage of time below range <3.0 mmol/L • Standard deviation (SD) – mmol/L • Coefficient of variation (CV) – SD divided by mean glucose level • Mean glucose – mmol/L • Hypoglycemia level 1 3.0-3.9 mmol/L – duration more than 15 consecutive minutes • Hypoglycemia level 2 <3.0 mmol/L – duration more than 15 consecutive minutes • Number of hypoglycemic events in level 1 and 2, respectively
Substudy 6 – medical file review	
Differences in interstitial and plasma glucose	• Differences in interstitial and capillary glucose

Figure 4 Outcome measures for substudy 1, 2, 3, 5 and 6. CGM, continuous glucose monitoring; CRP, C reactive protein; eGFR, estimated glomerular filtration rate; IE, international unit; POC, point-of-care; TIR, time-in-range.

the surgical ward used after discharge? Both interviews are audio recorded and scheduled for about 30 min each.

Data are collected from 34 of the 220 patients from substudy 1 by LA, TLT and MCP. If patients cancel or do not show up for their scheduled interview, they are contacted by phone or text message to follow-up (figure 1). 14 patients are included in period 1 and 20 patients in period 2.

Substudy 5: medical file review and continuous glucose levels

This study aims to compare continuous glucose levels when glucose monitoring and management are performed using POC FSGM versus POC CGMS in the surgical ward. Data are collected through a medical file review, based on sensor data from the CGMS used for POC in study period 2 and the blinded sensor in study period 3. The hypothesis is that POC CGMS will increase time in range and reduce the time with both hyperglycaemia and hypoglycaemia. Outcome measures will be reported according to consensus for inpatient CGM use,[25] of which some are listed in figure 4. Further variables will be analysed, that is, prolonged hypoglycaemia (>120 min) and recurring hypoglycaemic events after the first episode of hypoglycaemia. Some of the variables will be divided into daytime and nighttime. This study is conducted with 110 patients from substudy 1 in period 2 and 85 OUH patients from period 3.

Substudy 6: medical file review and accuracy of CGMS for surgical patients

This study investigates the accuracy of CGMS by comparing interstitial glucose measurements from CGMS with FSGM, capillary blood glucose measurements and plasma glucose laboratory blood samples (the gold standard). The hypothesis is that CGMS is as safe as capillary blood glucose for dosing insulin (see outcome measures in figure 4). Laboratory plasma glucose is added to the sample each time blood tests are prescribed. Data are collected from medical files. The study will be conducted only at OUH and includes the 85 patients from substudy 5.

Substudy 7: qualitative interviews of nursing staff's experiences

The objective of this study is to explore the nursing staff's experience with POC FSGM and POC CGMS in surgical patients. Data are collected through qualitative interviews. The inclusion criteria are nursing staff with at least 1 month's experience with both monitoring methods and registered nurses and certified nursing assistants. 24 nursing staff members (20 surgical nursing staff and four diabetes nurses from OUH) will be interviewed. A semi-structured interview guide is used to focus on the professionals' experience with the two glucose monitoring procedures and how the methods influence their actions, interactions and communication with patients. The interviews are scheduled for 30 min, are audio-recorded and are conducted at a time convenient for the nursing staff.

Data management and analysis

The power calculation for substudy 2 was derived from previous research on patient satisfaction with diabetes treatment, using the DTSQ-IP.[26 27] Item four, 'How convenient have you found your treatment,' was central to our study. In previous research, 65% reported the treatment as convenient.[26 27] An increase to 95% was considered possible, as patients in standard care get at least three finger-sticks daily compared with one stick in the upper arm every fortnight in the intervention group. To achieve a significance level of ≤0.05 with a power of 80% and accounting for a dropout rate of 10%, a sample size of 85 patients per group is required. With 110 participants in each group, power is above 80% in this study.

In substudy 5, we conducted a power analysis to determine the detectable difference in time-in-range (TIR) between the CGMS group and the FSGM group with blinded CGM. The power calculation assumed a SD of 25% in both groups, a two-sided significance level (α) of 0.05 and 110 participants in the intervention group and 85 in the control group (total n=195). These assumptions align with findings from the recent Danish DIATEC trial, which demonstrated a 15 percentage point increase in TIR when using CGM versus POC testing in hospitalised patients with type 2 diabetes.[17] The study achieves 70% power to detect a nine percentage point difference, 80% power to detect a 10 percentage point difference and 90% power to detect a 12 percentage point difference in TIR.

Quantitative data will be entered into a database in REDCap with range settings (V.13.7.18, 2024 Vanderbilt University, Tennessee, USA) and transferred to STATA (V.18.0; StataCorp, Texas, USA). For descriptive statistics, continuous variables will be summarised using means (SD) or medians (IQR) depending on normality, while categorical variables will be presented as frequencies (%). The normality of continuous variables will be assessed using the Shapiro-Wilk test. If normally distributed, differences between groups will be tested using independent t tests or analysis of variance. If non-normally distributed, Kruskal-Wallis tests will be applied. Categorical variables will be compared using χ^2 tests or Fisher's exact test, as appropriate.

Multiple linear regression will be performed to assess differences in glycaemic outcomes (daytime, nighttime and total day) between CGMS and FSGM groups in different models adjusting for potential confounders (eg, age, sex, BMI, baseline eGFR and HbA1c, number and type of surgery (major/minor/none), antibiotic-treated infections). Similarly, multivariable logistic regression will be used for binary outcomes (eg, presence of hypoglycaemia, complications).

Interaction terms will be included to explore whether effects differ by key subgroups (eg, age, sex, prior diagnosis of vs no diagnosis of diabetes, insulin-treated vs non-insulin-treated patients and surgery type (major/minor/none).

Bland-Altman plots will be used to assess agreement between CGMS and reference glucose measurements

(FSGM and laboratory plasma glucose). The analysis will estimate bias as the mean difference between CGMS and reference values, with 95% limits of agreement. In addition to Bland-Altman plots, error grid analysis (Parkes or Clarke) will categorise discrepancies based on their potential impact on clinical decision-making, ensuring a comprehensive assessment of CGMS accuracy in surgical patients.

Missing data will be addressed using multiple imputations with chained equations, assuming data are missing at random. The imputation process will include all covariates and outcomes to preserve the relationships between variables and minimise bias. A two-sided p value <0.05 will be considered statistically significant.

Qualitative data from participant observation and interviews will be stored in SharePoint with double login and transferred to the database programme NVivo (V.14.23.03). The text will be analysed through a Ricoeur-inspired method focused on narratives and interpretation. Participant experiences with FSGM will be compared with those with CGMS. The data will be treated as a text and analysed and interpreted at three levels: (1) a naïve reading gives an initial overall impression of the text; (2) a structural analysis structures the text in units of meaning (what is said) and units of significance (what is being talked about), and themes emerge from this process; (3) a critical interpretation and discussion will further analyse, interpret and discuss the themes with other research results.[28]

Trial management

The clinical trial sponsors are HS and KS. To facilitate the dissemination of trial results and author contributions, written cooperation agreements have been established between the surgical departments at OUH and SUH and between the surgical department at OUH and the Steno Diabetes Center Odense. Access to preliminary results is allocated to HS and KS.

A trial steering committee with monthly meetings, composed of the authors of this protocol, will deliberate and make a final decision regarding the trial's continuation if preliminary results or incidents during the trial necessitate adjustment or interruption. The trial sponsors are responsible for communicating any protocol modifications to data collectors.

Patient and public involvement

Patients actively participated in preparing the patient information materials, ensuring that they were clear, relevant and accessible to all participants. Patients and/or the public were not involved in the design, conduct, reporting or dissemination plans of this research.

ETHICS AND DISSEMINATION

The study follows the Declaration of Helsinki[29] and has been approved by the Regional Scientific Ethical Committee in Southern Denmark (ID number: S-20240041). Data are managed in accordance with the European Union's General Data Protection Regulation and the Danish data protection legislation. The study is registered at the records of processing activities in the Region of Southern Denmark regarding research and quality projects (ID number: 23/36734).

The GLUCOSENS trial will show qualitative and quantitative effects of in-hospital CGMS in combination with a team of specialised nurses to act on CGM data in managing hospitalised patients with hyperglycaemia in a general surgical ward. The study addresses an important issue of potential hypoglycaemia and hyperglycaemia in surgical patients and an issue of nursing staff shortage, where an innovative approach with CGMS might be beneficial in both cases. We expect that the CGMS will result in fewer fluctuations in glucose levels, increase patient satisfaction and free up time for other important parts of patient care by releasing about 5 hours of work for nursing staff daily for approximately 10 admitted diabetes patients. Another important issue in the study is the accuracy of CGM, as there are currently no studies comparing CGM glucose readings with those from a laboratory glucose analyser as the reference.

The risk of having a sensor on the arm is minimal, as mild skin irritations and bleeding have rarely been reported. However, the skin at the sensor will be observed continuously. No long-term side effects have been reported. In study period 2, precautions are taken by performing fingerstick monitoring when sensor glucose levels are below 4, above 16, when the patients show signs of hypoglycaemia or hyperglycaemia or when the reliability of the sensor results is questioned in the clinical setting. Patients will be withdrawn from the study intervention if a patient is no longer willing to continue participating in the study or if it is not possible for a patient to follow the study protocol. All patients are covered by the mandatory individual insurance.

We hope that the results from this study can generate hypotheses for further study interventions with wider use of CGMS, that is, interpretation of glucose directions revealed when scanning, diabetes nurses' interpretation of uploads, use of insulin Smartpens and telemetric CGM with alarms. The study results, positive, negative or inconclusive, will be published nationally and internationally.

Author affiliations
[1]Odense University Hospital Department of Surgery, Odense, Region of Southern Denmark, Denmark
[2]Department of Clinical Research, University of Southern Denmark, Odense, Denmark
[3]Zealand University Hospital Koge Department of Surgery, Koge, Region Zealand, Denmark
[4]University of Southern Denmark Department of Regional Health Research, Odense, Syddanmark, Denmark
[5]Steno Diabetes Center Odense, Odense University Hospital, Odense, Region of Southern Denmark, Denmark
[6]Odense University Hospital Department of Surgery, Svendborg, Region of Southern Denmark, Denmark

Contributors LA and HS initiated the study and performed the initial study protocol, which was further developed in collaboration with KS, ULJ and MCP. All authors made clinical adjustments to the study protocol. LA, KBN, TLT and TDN are primary data collectors. HS and KS made the draft of this paper, which all authors contributed to. HS (corresponding author) is the guarantor. I have used Copilot and Grammarly to enhance the grammar and language, as English is not my native language.

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ORCID iD

Helen Schultz http://orcid.org/0000-0003-4815-6349

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